



Patent Application

Attorney Docket No. PC25240A

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to: P.O. Box 1450, Alexandria, VA 22313 on this 24th day of February 2005.

By _____

(Signature of person mailing)

Arlene Carlson

(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Timothy A. Hagen, et al.

APPLICATION NO.: 10/763,340 : Examiner: To be assigned

FILING DATE: January 23, 2004 : Group Art Unit: 1615

TITLE: AZITHROMYCIN DOSAGE FORMS WITH REDUCED
SIDE EFFECTS

Hon. Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. § 1.97 ET SEQ.

Applicant(s) herein make(s) available to the U.S. Patent and Trademark Office a copy of PTO-FB-A820 which lists the references cited by the applicant(s), copies of which are enclosed.

A first Office Action on the merits has not been received; therefore, no fee for this Information Disclosure Statement is required. In the event that an Office Action has been mailed, please charge the appropriate fee to Deposit Account No. 16-1445.

The Examiner is requested to consider carefully the complete text of these references in connection with the examination of the above-identified application in accord with 37 C.F.R. § 1.104(a). It is believed the Examiner will concur with applicant's belief that the subject matter presently claimed is neither anticipated nor rendered obvious by the foregoing references.

It is requested that the references listed on the attached form PTO-FB-A820 be included in the "References Cited" portion of any patent issuing from this application (M.P.E.P. § 1302.12).

Respectfully submitted,

Date: Feb. 24, 2005

Lance Liu
Lance Y. Liu
Attorney for Applicant(s)
Reg. No. 45379

Pfizer Inc.
Patent Department, MS 8260-1611
Eastern Point Road
Groton, Connecticut 06340
(860) 686-1652



SUPPLEMENTAL INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i> Page 1 of 7								ATTY. DOCKET NO. PC25240A				SERIAL NO. 10/763,340			
								APPLICANT Timothy A. Hagen, et al.							
								FILING DATE January 23, 2004				GROUP 1615			
U.S. PATENT DOCUMENTS															
EXAMINE R INITIAL		DOCUMENT NUMBER							DATE	NAME		CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
US	2	9	5	5	9	5	6	10/11/1960	Baugh, et al.		117	100			
US	4	0	5	3	2	6	4	10/11/1977	King		425	8			
US	4	0	8	6	3	4	6	4/25/1978	Bocker, et al.		424	253			
US	4	0	9	2	0	8	9	5/30/1978	Bocker, et al.		425	10			
US	4	2	9	3	5	7	0	10/06/1981	Vadasz		426	3			
US	4	4	7	4	7	6	8	10/02/1984	Bright		424	180			
US	4	5	1	7	3	5	9	05/14/1985	Kobrehel, et al.		536	7.4			
US	4	6	7	5	1	4	0	06/23/1987	Sparks, et al.		264	4.3			
US	4	8	7	4	6	1	1	10/17/1989	Wilson, et al.		424	410			
US	4	9	3	1	2	8	5	06/05/1990	Edgren, et al.		424	473			
US	4	9	5	7	6	8	1	09/18/1990	Klimesch, et al.		264	211.23			
US	4	9	6	3	5	3	1	10/16/1990	Remington, et al.		514	29			
US	5	0	1	9	3	0	2	05/28/1991	Sparks, et al.		264	8			
US	5	0	2	4	8	4	2	06/18/1991	Edgren, et al.		424	473			
US	5	0	4	7	2	4	4	09/10/1991	Sanvordeker, et al.		424	435			
US	5	0	6	4	6	5	0	10/12/1991	Lew		424	435			
US	5	0	8	4	2	8	7	01/28/1992	Ghebre-Sellassie, et al		424	495			
US	5	1	0	0	5	9	2	03/31/1992	Sparks, et al.		264	7			
US	5	1	6	0	7	4	3	11/03/1992	Edgren, et al.		424	473			
US	5	1	4	3	6	6	2	09/1/1992	Chesterfield, et al.		264	8			
US	5	1	8	3	6	9	0	02/02/1993	Carr, et al.		427	213.31			
US	5	1	9	4	2	6	2	03/16/1993	Goldberg, et al.		424	401			
US	5	1	9	6	1	9	9	03/23/1993	Fuisz		424	401			
US	5	2	1	3	8	1	0	05/25/1993	Steber		424	490			
US	5	2	3	6	7	3	4	08/17/1993	Fuisz		426	641			
US	5	2	9	2	6	5	7	03/08/1994	Rutherford, et al.		435	243			
US	5	3	4	8	7	5	8	09/20/1994	Fuisz, et al.		426	660			

SUPPLEMENTAL INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i> Page 2 of 7							ATTY. DOCKET NO. PC25240A				SERIAL NO. 10/763,340		
							APPLICANT Timothy A. Hagen, et al.						
							FILING DATE January 23, 2004				GROUP 1615		
	US	5	3	8	0	4	7	3	01/10/1995	Bogue, et al.	264	11	
	US	5	4	0	5	6	1	7	04/11/1995	Gowan, Jr., et al.	424	464	
	US	5	4	0	7	6	7	6	04/18/1995	Fuisz	424	401	
	US	5	4	2	9	8	3	6	07/04/1995	Fuisz	426	601	
	US	5	4	3	3	9	5	1	07/18/1995	Serajuddin, et al	424	486	
	US	5	4	5	6	9	3	2	10/10/1995	Fuisz, et al	426	548	
	US	5	5	4	9	9	1	7	08/27/1996	Cherukuri, et al.	426	96	
	US	5	4	6	1	0	8	9	10/24/1995	Handyside, et al.	523	171	
	US	5	5	0	0	1	6	2	03/19/1996	Theisen, et al	264	9	
	US	5	5	0	1	8	5	8	03/26/1996	Fuisz	424	439	
	US	5	5	0	5	9	8	3	04/09/1996	Kamada	427	2.21	
	US	5	5	1	8	7	3	0	05/21/1996	Fuisz	424	426	
	US	5	5	3	9	0	0	0	07/23/1996	Leonard	514	682	
	US	5	5	4	9	9	1	7	08/27/1996	Cherukuri, et al.	426	96	
	US	5	5	5	6	6	5	2	09/17/1996	Cherukari, et al	426	5	
	US	5	5	6	9	4	6	7	10/29/1996	Ruiz	424	489	
	US	5	5	8	2	8	5	5	12/10/1996	Cherukuri	426	5	
	US	5	5	9	7	4	1	6	01/28/1997	Fuisz, et al.	127	30	
	US	5	5	9	7	8	4	4	01/28/1997	Chauhan, et al.	514	400	
	US	5	6	0	1	7	6	1	02/11/1997	Hoffman, et al.	264	4.3	
	US	5	6	8	3	7	2	0	11/04/1997	Myers, et al.	424	489	
	US	5	6	9	0	9	5	9	11/25/1997	Palepu, et al.	424	472	
	US	5	7	0	7	6	4	6	01/13/1998	Yajima, et al.	424	439	
	US	5	7	3	3	5	7	7	03/31/1998	Myers, et al.	424	488	
	US	5	7	4	1	5	1	9	04/21/1998	Rosenberg, et al.	424	464	
	US	5	7	4	4	1	8	0	08/28/1998	Cherukuri, et al	426	99	
	US	5	7	6	6	5	2	1	06/16/1998	Le Thiesse et al.	264	7	
	US	5	7	9	2	4	7	4	08/11/1998	Rauchfuss	424	489	

SUPPLEMENTAL INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i> Page 3 of 7							ATTY. DOCKET NO. PC25240A				SERIAL NO. 10/763,340		
							APPLICANT Timothy A. Hagen, et al.						
							FILING DATE January 23, 2004				GROUP 1615		
	US	5	8	2	4	3	4	2	10/20/1998	Cherukuri, et al.	424	484	
	US	5	8	4	0	3	3	4	11/24/1998	Raiden, et al	424	464	
	US	5	8	4	9	2	2	3	12/15/1998	Myers, et al.	264	15	
	US	5	8	5	1	5	5	3	12/22/1998	Myers, et al.	424	488	
	US	5	8	5	1	5	5	5	12/22/1998	Sanghvi, et al.	424	464	
	US	5	8	5	5	9	1	5	01/05/1999	Pinkus	242	486	
	US	5	8	6	9	0	9	8	02/09/1999	Misra, et al.	424	484	
	US	5	8	6	9	1	0	1	02/09/1999	Moller, et al	424	489	
	US	5	8	8	3	1	0	3	03/16/1999	Burnside, et al.	514	262	
	US	5	8	9	1	8	4	5	04/06/1999	Myers	514	11	
	US	5	9	1	2	0	3	0	06/15/1999	Huzinec, et al.	426	3	
	US	5	9	1	9	4	8	9	07/06/1999	Saleki-Gerhardt, et al.	424	501	
	US	5	9	3	5	6	0	0	08/10/1999	Cherukuri, et al.	424	464	
	US	5	9	4	8	4	0	7	09/07/1999	McGuinness, et al.	424	184.1	
	US	5	9	5	2	0	0	4	09/14/1999	Rudnic, et al.	424	455	
	US	5	9	5	8	4	5	2	09/28/1999	Oshlack, et al.	424	457	
	US	5	9	6	5	1	6	1	10/12/1999	Oshlack, et al.	424	457	
	US	5	9	6	5	1	6	4	10/12/1999	Fuisz, et al.	424	489	
	US	5	9	7	2	3	7	3	10/26/1999	Yajima, et al.	424	439	
	US	5	9	8	0	9	4	1	11/09/1999	Raiden, et al.	424	464	
	US	6	0	1	0	7	1	8	01/04/2000	Al-Razzak, et al.	424	464	
	US	6	0	1	3	2	8	0	01/11/2000	Frisbee, et al.	424	464	
	US	6	0	4	8	5	4	1	04/11/2000	Mirsa, et al.	424	401	
	US	6	0	5	1	2	5	3	04/18/2000	Zettler, et al.	424	465	
	US	6	0	7	7	5	4	1	06/20/2000	Chen, et al.	424	480	
	US	6	0	8	3	4	3	0	07/04/2000	Fuisz, et al.	264	5	
	US	6	0	8	6	9	2	0	07/11/2000	Frisbee, et al.	424	489	
	US	6	0	9	0	8	3	0	07/18/2000	Myers, et al.	514	356	

SUPPLEMENTAL INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i> Page 4 of 7							ATTY. DOCKET NO. PC25240A				SERIAL NO. 10/763,340		
							APPLICANT Timothy A. Hagen, et al.						
							FILING DATE January 23, 2004				GROUP 1615		
	US	6	1	0	3	2	6	4	08/15/2000	Hoffmann, et al.	424	468	
	US	6	1	1	7	4	5	2	09/12/2000	Ahlgren, et al.	424	468	
	US	6	1	3	9	8	7	2	10/31/2000	Walsh	424	464	
	US	6	1	6	5	5	1	2	12/26/2000	Mezaache, et al.	424	489	
	US	6	2	2	1	3	6	8	04/21/2001	Breitenbach, et al.	424	400	
	US	6	2	6	1	5	9	9	07/17/2001	Oshlack, et al.	424	457	
	US	6	2	6	8	4	8	9	07/31/2001	Allen, et al.	536	7.4	
	US	6	2	7	0	8	0	4	08/07/2001	Getz, et al.	424	490	
	US	6	3	2	8	9	9	3	12/11/2001	Linder, et al	424	451	
	US	6	3	3	5	0	3	3	01/01/2002	Oshlack, et al.	424	457	
	US	6	3	8	3	5	1	0	05/07/2002	Linder, et al.	424	436	
	US	6	3	9	5	3	0	0	05/28/2002	Straub, et al.	424	489	
	US	6	5	5	1	6	1	6	04/22/2003	Notario, et al.	424	464	
	2001	0	0	0	3	5	9	0	06/14/2001	Joachim, et al.	424	465	
	2001	0	0	0	6	6	5	0	07/05/2001	Burnside, et al.	424	400	
	2002	0	0	0	9	4	3	3	01/24/2002	Curatolo, et al	424	94.1	
	2002	0	0	2	5	3	4	2	02/28/2002	Linder, et al	424	489	
	2002	0	0	4	4	9	6	8	04/18/2002	Van Lengerich	424	469	
	2005	0	0	2	6	8	5	1	02/03/2005	Danilovski, et al.	514	28	
	US	5	6	0	5	8	8	9	02/25/1997	Curatolo, et al.	514	29	
	2003	0	2	2	8	3	5	7	12/11/2003	Johnson, et al.	424	465	
	2003	0	1	6	5	5	6	3	09/04/2003	Murphy, et al.	424	465	
	2003	0	1	9	0	3	6	5	10/09/2003	Fergione, et al.	424	489	
	US	4	9	6	3	5	3	1	10/16/1990	Remington	514	29	
	2004	0	0	1	4	9	5	1	01/22/2004	Dumic et al	536	7.1	
	US	6	3	6	5	5	7	4	04/02/2002	Singer et al.	514	29	
	US	6	2	4	5	9	0	3	06/12/2001	Karimian, et al.	536	7.4	
	2004	0	1	2	1	0	0	3	06/24/2004	Chickering, III et al.	424	465	

SUPPLEMENTAL INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i> Page 5 of 7							ATTY. DOCKET NO. PC25240A					SERIAL NO. 10/763,340				
							APPLICANT Timothy A. Hagen, et al.									
							FILING DATE January 23, 2004					GROUP 1615				
	US	6	6	8	9	3	9	0	02/10/2004	Bernstein, et al.	424	501				
	US	6	4	2	3	3	4	5	07/23/2002	Bernstein, et al.	424	501				
	US	6	6	4	5	5	2	8	11/11/2003	Straub, Ket al.	424	489				
FOREIGN PATENT DOCUMENTS																
DOCUMENT NUMBER									DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION			
													YES	NO		
	IN	1	8	7	4	8	7		24 May 00	Indian	A61K	9/10				
	WO	9	1	0	7	1	7	1	30 May 91	International	A61K	9/16				
	WO	9	4	0	0	1	1	2	06 Jan 94	International	A61K	9/22				
	WO	9	4	2	7	5	5	7	8 Dec 94	International	A61					
	WO	9	8	0	6	7	1	4	19 Feb 98	International	C07D	311/74				
	WO	9	8	4	6	2	3	9	22 Oct 98	International	A61K	31/71				
	WO	9	9	0	3	4	5	3	28 Jan 99	International	A61K	9/50				
	WO	9	9	2	4	0	3	1	20 May 99	International	A61K	31/40				
	WO	0	0	2	6	2	8	5	11 May 00	International	C08K	5/103				
	WO	0	0	5	7	8	8	6	05 Oct 00	International	A61K	31/70				
	WO	0	1	4	2	2	2	1	14 Jun 01	International	C07D	231/12				
	WO	0	1	7	8	6	8	8	25 Oct 01	International	A61K	9/24				
	WO	0	1	8	5	1	3	5	15 Nov 01	International	A61K	9/00				
	WO	0	2	2	4	1	7	4	28 Mar 02	International	A61K	6/50				
	WO	4	0	3	5	0	6	3	29 Apr 04	International	A61K	31/7048				
	WO	3	0	3	2	9	2	2	24 Apr 03	International	A61K					
	WO	4	0	0	9	6	0	8	29 Jan 04	International	C07H	17/00				
	WO	3	0	6	8	1	9	1	21 Aug 03	International	A61K	9/14				
	WO	4	0	8	7	0	9	6	14 Oct 04	International	A61K	9/00				
	WO	3	1	0	5	8	1	0	24 Dec 03	International	A61K	9/20				
	EP	0	0	8	0	3	4	1	01 Jun 83	EPO	A61K	9/22				
	EP	0	1	0	9	2	5	3	23 May 84	EPO	C07H	17/00				

SUPPLEMENTAL INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i> Page 6 of 7							ATTY. DOCKET NO. PC25240A				SERIAL NO. 10/763,340		
							APPLICANT Timothy A. Hagen, et al.						
							FILING DATE January 23, 2004				GROUP 1615		
	EP	0	5	8	2	3	9	6	09 Feb 94	EPO	A61K	31/71	
	EP	0	7	7	6	6	5	8	16 Feb 00	EPO	A61K	7/50	X
	EP	0	9	4	3	3	4	1	22 Sep 99	EPO	A61K	47/48	
	EP	1	1	2	7	5	8	0	29 Aug 01	EPO	A61K	47/10	
	EP	0	9	2	5	7	8	9	30 Jun 99	EPO	A61K	31/7052	
	EP	1	1	2	7	5	8	0	29 Aug 01	EPO	A61K	47/10	
	GB	2	0	6	6	0	7	0	08 Jul 81	United Kingdom	A61K	9/36	
	GB	2	0	9	1	0	9	7	28 Jul 82	United Kingdom	A61K	9/36	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)													
			Barber, J., "Assignments of the ¹³ C and ¹ H NMR Spectra of Azithromycin in CDCl ₃ ," <i>Magnetic Resonance in Chemistry</i> 29:7(1991)740-743.										
			Barthelemy, P., et al., "Compritol® 888 ATO: An Innovative Hot-Melt Coating Agent for Prolonged-Release Drug Formulations," <i>Europ. J. Pharmaceut. and Biopharmaceutics</i> , 47(1999)87-90.										
			Bhagwatwar, H., et al., "Preparation of Drug-Containing Wax Microspheres Using a Melt Dispersion Technique," <i>Pharmaceutical Research</i> , 6:7(1989)S-177, Abstract No. PD 1201.										
			Breitenbach, J., et al., "Solid Dispersions by an Integrated Melt Extrusion System," <i>Proceed. Int'l Symp. Control. Re. Bioact. Materials</i> , 25(1998)804-805										
			Craig, D.Q.M., "The Physical Characterisation of Gelucire 50/13," <i>Bulletin Technique Gattefosse</i> , 89(1996)39-51.										
			DeMan, J.M., et al., "Thermal Analysis Microscopy for the Study of Phase Changes in Fats," <i>Food Microstructure</i> , 4(1985)233-239.										
			Eldem T., et al., "Polymorphic Behavior of Sprayed Lipid Micropellets and Its Evaluation by Differential Scanning Calorimetry and Scanning Electron Microscopy," <i>Pharmaceutical Research</i> , 8:2(1991)178-184.										
			Eldem, T., et al., "Optimization of Spray-Dried and -Congealed Lipid Micropellets and Characterization of Their Surface Morphology by Scanning Electron Microscopy," <i>Pharmaceutical Research</i> , 8:1(1991)47-54										
			Emas, M., and H. Nyqvist, "Methods of Studying Aging and Stabilization of Spray-Congealed Solid Dispersions with Carnauba Wax. 1. Microcalorimetric Investigation," <i>Int'l J. Pharmaceutics</i> , 197(2000)117-127.										
			Faham, A., et al., "Hot-Melt Coating Technology. I. Influence of Compritol 888 Ato and Granule Size on Theophylline Release," <i>Drug Dev. Industrial Pharm.</i> , 26:2(2000)167-176.										
			Follonier, N., et al., "Hot-Melt Extruded Pellets for the Sustained Release of Highly Dosed Freely Soluble Drugs," <i>Proceed. Intern. Symp. Control. Release Bioactive Materials</i> , 18(1991)578-579.										
			Forster, A., et al., "Characterization of Glass Solutions of Poorly Water-Soluble Drugs Produced by Melt Extrusion with Hydrophilic Amorphous Polymers," <i>J. Pharmacy Pharmacology</i> , 53(2001)303-315.										
			Foulds, G., et al., "The Absence of an Effect of Food on the Bioavailability of Azithromycin Administered as Tablets, Sachet or Suspension," <i>J. Antimicrobial Chemotherapy</i> , 37:Suppl. C(1996)37-44.										
			Gattefosse, "Gelucire® - Pharmaceutical Excipients for Oral Semi-Solid Formulations," Technical Dossier, 2 nd edition, Gattefosse s.a., Cedex, France (1996).										
			Ghali, E.S., et al., "Thermal Treatment of Beads with Wax for Controlled Release," <i>Drug Development and Industrial Pharmacy</i> , 15:9(1989)1311-1328.										
			Hancock, B.C., and G. Zografi, "The Relationship Between the Glass Transition Temperature and the Water Content of Amorphous Pharmaceutical Solids," <i>Pharmaceutical Research</i> , 11:4(1994)471-477.										
			Joachim, J., et al., "Le Compritol*, Etudes Galénique, Physique et Statistique," APGI, IV(1989)291-296.										
			Johnson, D.E., et al., "A New Method for Coating Glass Beads for Use in Gas Chromatography of Chloropromazine and Its Metabolites," Source unknown, and date unknown. (May be 1964-1965)										
			Jorgensen, K., et al., "Dissolution Stability of Multiparticulate Controlled Release Tablets," <i>Int'l J. Pharmaceutics</i> , 153(1997)1-11.										

SUPPLEMENTAL INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i> Page 7 of 7			ATTY. DOCKET NO. PC25240A	SERIAL NO. 10/763,340
			APPLICANT Timothy A. Hagen, et al.	
			FILING DATE January 23, 2004	GROUP 1615
<p>Meshall, M.M., et al., "Optimization of Theophylline Release from Tablets Containing Compritol," <i>S.T.P. Pharma Sciences</i>, 5:6(1995)429-434.</p> <p>Perez, M. deLos A, et al., "Sustained Release Phenylpropanolamine Hydrochloride from Compritol ATO-888 Matrix," <i>Pharmaceutical Research</i>, 9:10(1992)S-162, Abstract No. PT6191.</p> <p>Perez, M.A., et al., "Sustained Release Phenylpropanolamine Hydrochloride from ATO 888 Matrix," <i>PRHSJ</i>, 12:4(1993)263-267.</p> <p>Perissutti, B., et al., "Solid Dispersions of Carbamazepine with Gelucire 44/14 and 50/13," <i>S.T.P. Pharma Sciences</i>, 10:6(2000)479-484.</p> <p>Physician's Desk Reference, Information cited on ZITHROMAX® capsules (equivalent to 250 mg azithromycin), tablets (equivalent to 600 mg azithromycin), and oral suspension (equivalent to 1 g azithromycin).</p> <p>Reilly, W.J. Jr., and J.B. Schwartz, "A Potential Controlled Release Wax Matrix Excipient," <i>Pharmaceutical Research</i>, 8:10(1991)98, supplement, Abstract No. PT6108.</p> <p>Reis, R. and F. Moll, "Matrix Formation of Polyglycolic Acid Tablets by Annealing," <i>European J. Pharm. and Biopharm.</i>, 40:1(1994)14-18.</p> <p>Rxlist.com, "Azithromycin," description of drug, categories, brand names, from internet website, March 14, 2001.</p> <p>San Vincente, A., et al., "Effect of Aging on the Release of Salbutamol Sulfate from Lipid Matrices," <i>Int'l J. Pharmaceutics</i>, 208(2000)13-21.</p> <p>Schwartz, J.B., et al., "A Potential Controlled Release Wax Matrix Excipient for Tablets," <i>Pharmaceutical Research</i>, 9:10(1992)S-162, Abstract No. PT6189</p> <p>Schwartz, J.B., et al., "Preliminary Evaluation of Controlled Release Agents for Tablets, <i>Pharmaceutical Research</i>, 9:10(1992)S-162, Abstract No. PT6190.</p> <p>Sugao, H., et al., "Taste Masking of Bitter Drug Powder without Loss of Bioavailability by Heat Treatment of Wax-Coated Microparticles," <i>J. Pharmaceutical Sci.</i>, 87:1(1998)96-100.</p> <p>Thomsen, L.J., et al., "Prolonged Release Matrix Pellets Prepared by Melt Pelletization. I. Process Variables," <i>Drug Development and Industrial Pharmacy</i>, 19:15(1993)187-1887.</p> <p>Wang, A.E. and J.B. Schwartz, "Effect of Temperature on Drug Release from Wax Matrix Tablets After Thermal Treatment," <i>Pharmaceutical Research</i>, 11:10(1994)S-155, Abstract No. 6099.</p> <p>Zhang, Y.-E., et al., "Effect of Processing Methods and Heat Treatment on the Formation of Wax Matrix Tablets for Sustained Drug Release, <i>Pharm. Dev. Technol.</i>, 6:2(2001)131-144.</p> <p>Arguendas, A., "Single Dose Therapy in Otitis Media, <i>Clinical Microbiology and Infection</i>," Abstract, S130, vol. 5, Supplemental 3, (1999)</p> <p>Block, S., et al., "Single-Dose Azithromycin (30 mg/kg) in Acute Otitis Media," ICAAC, New Orleans, LA, Sept 7-10, 2003, Abstract 174</p> <p>Curatolo, W., et al., "Site-Specific Absorption and Toleration of Azithromycin," <i>Proceedings Intern. Symposium Rel. Bioact. Mater.</i>, 23, 1996</p> <p>Luke, D.R., et al, "Clinical Pharmacology of Azithromycin Given at Various Sites Along the Gastrointestinal Tract in Healthy Subjects," pp. 464-468</p> <p>Physicians Desk Reference, "Appendix A Summary of Pediatric Suspension Commercial Products," 55th edition, Phase III Clinical Dosage Form Nomination, pp 19 and 28 (2001)</p> <p>Pfizer, Inc., Zithromax [package insert], "Zithromax (azithromycin tablets) and (azithromycin for oral suspension)," www.pfizer.com/download/uspi_zithromax.pdf (2004)</p>				
EXAMINER			DATE CONSIDERED	
<p>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>				